

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA WOMEN'S HEALTH, INC.,

Plaintiff/Counterclaim-
Defendant,

v.

LUPIN, LTD., LUPIN
PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC. and WATSON
PHARMACEUTICALS, INC.,

Defendants/Counterclaim-
Plaintiffs.

TEVA WOMEN'S HEALTH, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC.,
MYLAN INC. and FAMY CARE LTD.,

Defendants/Counterclaim-
Plaintiffs.

Civil Action No. 10-080(FSH)(PS)

Civil Action No. 10-1234(FSH)(PS)

**PLAINTIFF'S BRIEF IN OPPOSITION TO LUPIN'S APPEAL FROM THE
MAGISTRATE JUDGE'S ORDER DENYING LUPIN'S MOTION FOR LEAVE
TO AMEND ITS PATENT INVALIDITY CONTENTIONS**

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I. INTRODUCTION

On December 31, 2010, Magistrate Judge Shwartz correctly denied Lupin's motion to amend its Local Patent Rule 3.3 Invalidity Contentions to add German Patent Application No. DE 195 25 071 ("the German Application") for failure to satisfy the good cause requirement of Local Patent Rule 3.7. (D.I. 136.) Nonetheless, Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") appeal Judge Shwartz's order. As established by Federal Circuit precedent, Lupin's failure (and inability) to demonstrate diligence in amending its Contentions is fatal to its motion. Thus, Plaintiff Teva Women's Health, Inc. ("TWH") respectfully requests that the Court uphold Judge Shwartz's well-reasoned decision to deny Lupin's request to amend its Invalidity Contentions.

II. RELEVANT FACTS

Lupin's recitation of the facts is incomplete and incorrect. Notably absent from Lupin's motion is the fact that Lupin had a copy of the German Application well before this lawsuit began. Lupin was also aware of the relevance of the German Application and its near-identical U.S. counterpart, Patent No. 6,027,749 ("the '749 patent"), to its invalidity allegations. Indeed, Lupin relied heavily on the '749 patent in its Detailed Statement of Factual and Legal Basis for Invalidity that it sent to TWH on November 24, 2009, more than a month before this lawsuit was filed. Lupin also neglects to inform the Court that the '749 patent identifies the German Application on its face, and its prosecution history includes full copies of both German and English-language versions of the German Application. In the end, it took Lupin over a year after receiving the German Application to seek to add it to its Invalidity Contentions.

Below is a timeline of facts relevant to Lupin's appeal:

Nov. 18, 2009: Lupin's counsel receives a copy of the German Application. Later that month, Lupin's counsel has its "in-house translator" create an English language

translation of portions of the German Application's specification, but not the claims. (D.I. 125 ¶ 1.)

Nov. 24, 2009: Lupin provides TWH with notice of Lupin's Paragraph IV certification for the patent-in-suit in this litigation, and a Detailed Statement of Factual and Legal Basis for Invalidity of the patent-in-suit.

Lupin's Detailed Statement relies heavily on the U.S. counterpart to the German Application, the '749 patent, even though Lupin acknowledges that the '749 patent "is inconsistent on the point of whether the extended period of [combination pill] administration is for a maximum of 77 days or 84 days" (Ex. A, Lupin's Nov. 24, 2009 Notice Ltr., at 18.)

Jan. 6, 2010: TWH files suit against Lupin alleging that Lupin's ANDA for generic LoSeasonique® infringes the patent-in-suit.

Jun. 7, 2010: Lupin serves its Local Patent Rule 3.3 Invalidity Contentions alleging obviousness based on the '749 patent and other references, but does not allege anticipation by any reference.

Consistent with its November 24, 2009 Detailed Statement, Lupin's Invalidity Contentions rely heavily on the '749 patent, even though Lupin acknowledges that it is "inconsistent as to whether the extended period of [combination pill] administration is for a maximum of 77 or 84 days" (Ex. B, Lupin's June 7, 2010 Invalidity Contentions, at 4.)

Jun. 30, 2010: Watson produces to all parties the prosecution history of the '749 patent, including both the German Application and a verified English translation.

Jul. 22, 2010: TWH responds to Lupin's interrogatories, in part, by noting Lupin's statements in its November 24, 2009 Detailed Statement and June 7, 2010 Invalidity Contentions, that the '749 patent does not clearly disclose the administration of 84 days of a combination pill (as opposed to a "maximum" of 77 days). (Ex. C, TWH's Resps. To Lupin's 1st Interrogs., at 10.)

Oct. 8, 2010: Lupin files a motion to amend its Answer to "provide[] an additional example of invalidity," which refers to the German Application.

Nov. 29, 2010: Lupin requests leave to amend its Invalidity Contentions under Local Patent Rule 3.7.

Despite Lupin's early knowledge of the German Application and its relevance to its invalidity contentions vis-a-vis the German Application's U.S. counterpart, Lupin delayed in seeking to amend its Invalidity Contentions to add the German Application until November 29, 2010, more than a year after it acknowledges having that reference. Thus, as discussed below,

Lupin's lack of diligence precludes it from meeting the good cause requirement of Local Patent Rule 3.7 for amending its Invalidity Contentions to add the German Application.

III. ARGUMENT

A. Magistrate Judge Schwartz's Decision Should Be Reviewed With Deference.

Lupin asserts that Magistrate Judge Schwartz's decision should be reviewed de novo, but fails to cite a single case where a denial (or grant) of a motion to amend local patent rule contentions was reviewed under that standard. Nor could it because such non-dispositive motions are reviewed deferentially under the clearly erroneous or contrary to law standard. 28 U.S.C. § 636(b)(1)(A) ("A judge of the court may reconsider any pretrial matter . . . where it has been shown that the magistrate judge's order is clearly erroneous or contrary to law"); Fed. R. Civ. P. 72(a) ("The district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law.").

The Federal Circuit has directly addressed contentions required by local patent rules like those of this Court, holding them to be a discovery mechanism rather than a dispositive matter:

[D]iscovery is designed to allow the defendant to pin down the plaintiff's theories of liability and to allow the plaintiff to pin down the defendant's theories of defense, thus confining discovery and trial preparation to information that is pertinent to the theories of the case . . . If the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a *mechanism for shaping the conduct of discovery* and trial preparation.

O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1365-66 (Fed. Cir. 2006).¹

"A magistrate judge's rulings concerning discovery, including sanction orders, are non-dispositive motions." *Wachtel v. Guardian Life Ins. Co.*, 239 F.R.D. 376, 384 (D.N.J. 2006). A motion as to a "mechanism for shaping the conduct of discovery" is such a non-dispositive discovery matter. *See O2 Micro*, 467 F.3d at 1366. Indeed, in affirming the magistrate judge's

¹ All emphases are added unless otherwise indicated.

decision to deny O2 Micro's motion to amend its contentions, the district court in *O2 Micro* applied the deferential standard for non-dispositive motions. *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, Nos. C-00-4071, C-01-3995, slip op. at 2 (N.D. Cal. Aug. 5, 2003) (Ex. D).

Moreover, Lupin itself has treated its motion to amend its invalidity contentions as a non-dispositive discovery motion. To make its motion, Lupin followed Magistrate Judge Schwartz's procedure for raising discovery disputes, namely filing a joint letter outlining the parties' positions in an informal application for relief. (D.I. 112.) In contrast, to seek leave to amend its pleadings, Lupin filed formal motion papers, and the parties filed three rounds of formal briefs. (D.I. 93, 101, 108.)

Lupin's authorities do not hold otherwise or support its argument. Lupin's motion to amend its Invalidity Contentions does not involve any money damages award. *Cf. Bennett v. Gen. Caster Serv.*, 976 F.2d 995, 998 (6th Cir. 1992). Nor does it involve effectively dismissing any claim or defense with *res judicata* effect through a Rule 37 sanction. *Cf. Ocelot Oil Co. v. Sparrow Indus.*, 847 F.2d 1458, 1462 (10th Cir. 1988); *Am. Stock Exchange, LLC v. Mopex, Inc.*, 215 F.R.D. 87, 92-93 (S.D.N.Y. 2002). Indeed, Lupin's Amended Answer only cites the German Application as an "example" of prior art allegedly supporting its anticipation defense. (D.I. 124.) Thus, contrary to Lupin's argument, Judge Schwartz's order denying Lupin's motion to amend its Invalidity Contentions did not effectively dismiss Lupin's anticipation claim and defense. For example, were Lupin to discover truly new prior art and, unlike here, diligently seek to amend its Contentions to add that new art as anticipatory, its anticipation defense could be asserted at trial.

Because Magistrate Judge Schwartz's decision denying Lupin's motion to amend its Invalidity Contentions is a non-dispositive discovery matter, it should be reviewed under the

deferential clearly erroneous or contrary to law standard. 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); *Wachtel*, 239 F.R.D. at 384.

B. Diligence Is Required To Establish Good Cause To Amend Local Patent Rule Contentions.

Judge Shwartz correctly relied on the Federal Circuit’s decision in *O2 Micro* to find that Lupin failed to demonstrate diligence, which is required to amend local patent rule contentions. Local Patent Rule 3.7 provides that a party may only amend its contentions upon a showing of “good cause.” L. Pat. R. 3.7. The *O2 Micro* decision could not be clearer: “We agree with the Northern District of California that ‘good cause’ *requires a showing of diligence.*” *O2 Micro*, 467 F.3d at 1366. Thus, while not the sole component required to establish “good cause,” diligence is a *necessary* component.

Nevertheless, Lupin argues that *O2 Micro* should *not* be understood to hold that “‘good cause’ requires a showing of diligence.” Instead, Lupin argues that the case law requires all “equitable” factors to be considered, regardless of whether diligence can be established. Yet *O2 Micro* expressly rejected that argument: “[W]e reject *O2 Micro*’s apparent argument that ‘good cause’ must exist for amending its infringement contentions, *without regard to its diligence in doing so*, merely because new evidence was revealed during discovery.” *Id.* Lupin neglects to mention that *O2 Micro* expressly set aside arguments as to other factors because of the patentee’s failure to meet the requirement of diligence: “Having concluded that . . . *O2 Micro* did not act diligently in moving to amend its infringement contentions, we see *no need to consider the question of prejudice.*” *Id.* at 1368. There is simply no discussion in *O2 Micro* of any other “equitable” factor—there was no need because the Federal Circuit concluded that the patentee fell short of the first hurdle by failing to demonstrate diligence. *Id.* at 1367-68.

Lupin's remaining attempts to distinguish *O2 Micro* are equally meritless. First, Lupin argues that because *O2 Micro* is an appellate decision, its applicability is somehow limited. Lupin's reasoning is unclear, but to the extent Lupin argues that Magistrate Judge Schwartz erred by failing to make sufficient factual findings, it is incorrect. Judge Schwartz made adequate findings as to Lupin's lack of diligence, and conducted a thorough inquiry into the issue. Indeed, even after the parties' detailed positions and supporting evidence were submitted, Judge Schwartz ordered the parties to submit still additional evidence concerning diligence. (D.I. 123.) And, as already discussed, Judge Schwartz properly concluded that Lupin's motion should be denied once she found that Lupin failed to act with diligence. (D.I. 136.) To the extent Lupin now argues it was error for Judge Schwartz not to make findings as to all possible "equitable" factors regardless of her findings as to diligence, that argument fails. *O2 Micro*, 467 F.3d at 1368.

Second, Lupin argues that *O2 Micro* only held that "some showing of diligence might be required to establish good cause." (Lupin Br. at 12.) As an initial matter, Lupin's attempted paraphrase of *O2 Micro* is refuted by the actual language of the opinion: "'good cause' *requires* a showing of diligence." *O2 Micro*, 467 F.3d at 1366. Further, to the extent Lupin is implying that a sliding scale should apply to diligence, the Federal Circuit held otherwise. Not only is there no mention of any such sliding scale in *O2 Micro*, but the Federal Circuit stated: "The burden is on the movant to establish diligence rather than on the opposing party to establish a lack of diligence." *Id.* Thus, it was Lupin's burden to "establish diligence," not provide some unspecified quantum of diligence evidence to meet a sliding scale.

Third, Lupin argues that *O2 Micro* does not "require courts to focus solely on diligence or to ignore other equitable factors when making an initial determination on the merits." (Lupin Br. at 12.) This argument is inapposite. While there are instances where other factors should be

considered, that is not the case here. As already discussed, Lupin's failure to establish diligence is fatal to its motion because "'good cause' *requires* a showing of diligence." *O2 Micro*, 467 F.3d at 1366.

Lupin's other authorities also do not support its arguments. For example, in the *Stanford* case, the district court expressly found that Stanford had acted diligently at least in notifying Roche of its amended positions, and Roche explicitly addressed those positions to its advantage during claim construction, even if it was "arguabl[e]" whether Stanford had been diligent in pursuing the amendment with the court. *Bd. of Trustees of Leland Stanford Jr. Univ. v. Roche Molecular Sys., Inc.*, No. C 05-04158, 2008 WL 624771, at *3 (N.D. Cal. Mar. 4, 2008). In the *King Pharms.* case, the Court did not reach the issue of diligence because it based its denial of a motion to amend contentions on the manifest prejudice that would ensue. *King Pharms., Inc. v. Sandoz Inc.*, No. 08-5974-GEB, 2010 WL 2015258, at *5 (D.N.J. May 20, 2010). Even though the defendant in *King* "could have been more diligent," the Court recognized that whether the defendant met the diligence requirement was moot because the plaintiffs would have been unfairly prejudiced. *Id.* at *4-5. This is similar to *O2 Micro*, where the Federal Circuit noted that the issue of prejudice was moot because O2 Micro had failed to meet the diligence requirement. *O2 Micro*, 467 F.3d at 1368. By the same token, nothing in *O2 Micro* prohibits a district court from examining equitable factors as appropriate, but the Federal Circuit expressly held that a court need not look further than diligence if that requirement is not met. *Id.* at 1368.

C. Magistrate Judge Schwartz Properly Applied The Diligence Requirement And Correctly Found That Lupin Did Not Meet It.

Judge Schwartz correctly applied the diligence requirement in finding that Lupin had not acted diligently with respect to the German Application. However, Lupin argues that Judge Schwartz misapplied the diligence requirement. In essence, Lupin argues that because it

supposedly failed to “appreciate” the German Application until late August 2010, Judge Shwartz should have been compelled to grant its motion. That is not the law.

“The critical issue is not *when* [the party seeking to amend its contentions] discovered this information, but rather, whether they *could have* discovered it earlier had it acted with the requisite diligence.” *See, e.g., Google, Inc. v. Netlist, Inc.*, No. C-08-4114-SBA, 2010 WL 1838693, at *2 (N.D. Cal. May 5, 2010) (emphasis in original). The logic of this rule is clear—otherwise, a party could always establish diligence simply by asserting that it did not subjectively “appreciate” the information until a later date.²

Despite Lupin’s arguments to the contrary, this rule is consistent with *O2 Micro*. Lupin first asserts, without citing to any portion of the Federal Circuit’s opinion, that *O2 Micro* holds that “diligence is evaluated from the time the movant *actually discovers and appreciates* new information.” (Lupin Br. at 14 (emphasis in original).) No such holding appears anywhere in *O2 Micro*. Nor do the facts of *O2 Micro* support Lupin’s interpretation. In fact, the Federal Circuit stated that the movant had received a document through discovery that could have informed it of the information it claimed to have only discovered and appreciated a year later. *O2 Micro*, 467 F.3d at 1367. The Court further stated that “[e]ven accepting *O2 Micro*’s contention” that it did not appreciate the information until a deposition a year later, the subsequent three-month delay alone was enough to justify the district court’s finding of no diligence. *Id.* In other words, the timing of *O2 Micro*’s claimed “appreciation” of the information did not impact the Federal Circuit’s decision.

² Lupin additionally argues that the fact that its co-defendants also did not “appreciate” the relevance of the German Application supports its argument. However, not only are the actions of Lupin’s co-defendants irrelevant to its own lack of diligence, but those actions only establish that its co-defendants *also* were not diligent in seeking leave to add the German Application to their Invalidity Contentions, as Judge Shwartz found. (D.I. 136.)

The facts of the present case are similar to those of *O2 Micro*. Lupin first received the German Application as well as translations of portions thereof in November 2009, a few days before it sent its notice of Paragraph IV certification and Detailed Statement of Factual and Legal Basis for Invalidity to TWH. Lupin was also aware of the nearly identical U.S. counterpart to the German Application, the ‘749 patent, which cites the German Application on its face. Indeed, Lupin even relied on the ‘749 patent in both its November 2009 Detailed Statement and its June 7, 2010 Invalidity Contentions. To the extent Lupin failed to obtain a complete translation of the German Application in the previous six months in which it had the German Application in its possession, Lupin’s co-defendant, Watson, provided Lupin with a complete, verified English translation no later than June 30, 2010. Yet Lupin’s request to amend its Contentions was not submitted until November 2010, a year after it first received the German Application and five months after it received a full English translation. Similar to *O2 Micro*, the facts demonstrate that Lupin was not diligent in seeking to amend its Contentions to add the German Application.

Lupin’s attempts to justify its lack of diligence are without merit. Lupin points to TWH’s July 2010 interrogatory response as the impetus for its “discovery” of the importance of the German Application. As an initial matter, the relevance of the German Application should have been readily apparent to Lupin because it is nearly identical to the ‘749 patent. Moreover, the ‘749 patent cites the German Application on its face, and Lupin had already had the German Application in its possession since November 2009—over half a year by the time TWH provided its July 2010 interrogatory response. Further, Lupin incorrectly asserts that the German Application discloses administering 84 daily doses of combination pills. Rather, the file history of the related ‘749 patent establishes the exact *opposite* fact—the ‘749 patent (and by extension

its counterpart German Application) should be understood as *not* disclosing a maximum of 84 daily doses of combination pills, but instead disclosing a maximum of 77 daily doses. (*See* D.I. 112 at 9-10.)

Moreover, all of the information in TWH's July 2010 interrogatory response was readily available to Lupin well before this litigation was even filed. TWH's interrogatory response merely pointed out Lupin's acknowledgement in its November 24, 2009 Detailed Statement of Factual and Legal Basis for Invalidity (and June 7, 2010 Invalidity Contentions) that "it is not clear if the '749 patent teaches 77 days or 84 days of administering a combination pill." (Ex. C, TWH's Resps. To Lupin's 1st Interrogs., at 10; *see also* Ex. A, Lupin's Nov. 24, 2009 Notice Ltr., at 18; Ex. B, Lupin's June 7, 2010 Invalidity Contentions, at 4.) Lupin's lack of diligence is not mitigated by the fact that TWH pointed to something Lupin itself had stated before this litigation was even filed.

Lastly, Lupin's complaints that voluminous document productions hampered its ability to "discover" the relevance of the German Application are unpersuasive at best. Lupin first received the German Application in November 2009 as it was preparing its ANDA notice letter to TWH, including its Detailed Statement of the bases for its Paragraph IV certification. No documents had been produced; indeed, the present case had yet to be filed. Even when considering only the copies of the German Application and its English translation provided to Lupin on June 30, 2010, the importance of those documents should have been clear given that they were part of the prosecution history of the '749 patent. Lupin had already relied on the '749 patent in its Invalidity Contentions, and it was well aware of the importance of the '749 patent and its prosecution history. Moreover, Lupin did not move to amend its Contentions for another five months after the June 30, 2010 production.

In sum, the facts and relevant authorities demonstrate that Magistrate Judge Schwartz's finding that Lupin was not diligent was manifestly correct, and certainly not clearly erroneous or contrary to law. Under the Federal Circuit's decision in *O2 Micro*, the denial of Lupin's motion to amend its Contentions should be upheld on that basis alone.

D. TWH Would Be Unfairly Prejudiced By Lupin's Proposed Amendment.

The Federal Circuit has held that the issue of prejudice need not be reached if a lack of diligence is found. *O2 Micro*, 467 F.3d at 1368. However, even if this Court were to reach the issue, Judge Schwartz's decision here should be upheld because TWH would be prejudiced by Lupin's proposed amendment to its Invalidity Contentions. Since receiving Lupin's Contentions on June 7, 2010, TWH has relied on those positions in developing its case. If Lupin were permitted to make its belated amendments to its Contentions as it seeks, TWH would be forced to expend significant resources revising its positions and litigation strategy.³ See *Softvault Sys., Inc. v. Microsoft Corp.*, No. 2:06-cv-16, 2007 WL 1342554, at *2 (E.D. Tex. May 4, 2007) (finding prejudice where allowing amendment would "forc[e] Microsoft to incur additional expense in reassessing its invalidity analyses").

The Local Patent Rules were designed precisely to avoid this sort of prejudice. See *O2 Micro*, 467 F.3d at 1365-66; see also *Motorola, Inc. v. Analog Devices, Inc.*, No. 1:03-cv-131, 2004 WL 5633736, at *1 (E.D. Tex. Apr. 20, 2004) ("Allowance of continuous amendments to infringement contentions and claim constructions would encourage the vexatious shuffling of positions that the local patent rules were designed to avoid." (internal quotation marks omitted)).

³ Lupin appears to argue that co-defendant Watson's anticipation defense lessens the prejudice to TWH. However, Watson's anticipation defense is based on the '749 patent, not the German Application. Watson, as well as co-defendants Mylan and Famy Care, also sought leave to amend their Contentions to add the German Application, but their motions were also denied for lack of good cause. (D.I. 136.) None of Lupin's co-defendants have appealed. Thus, if Lupin's motion were granted, TWH would be prejudiced by being forced to revise its positions and strategy to account for the German Application for the first time.

Indeed, Lupin continues to signal its intention to change its Contentions again later in the case by improperly reserving the right to do so irrespective of the Local Patent Rules or the Court's rulings: "Lupin reserves all of its rights to supplement, amend and modify the contentions made herein" (D.I. 113 at 1-2 (Lupin's proposed Amended Invalidity Contentions).) Such attempts to "reserve" the right to continuously amend contentions inherently violate the Local Patent Rules. *See Convolve, Inc. v. Compaq Computer Corp.*, No. 00 Civ. 5141-GBD-JCF, 2006 WL 2527773, at *4-5 (S.D.N.Y. Aug. 31, 2006) (holding that reserving the right to amend violated the purpose of the Local Patent Rules as well as the court's scheduling order).

E. The Federal Circuit Has Already Rejected Lupin's Arguments That The Local Patent Rules Are Inconsistent With The Federal Rules Of Civil Procedure.

Lupin argues that the Judge Shwartz was "overly rigid" in her application of the Local Patent Rules such that the Rules are in "tension with the Federal Rules of Civil Procedure, arguably to the point of conflict." (Lupin Br. at 8-9.) Essentially, Lupin argues that its motion to amend its Contentions should have been granted irrespective of whether diligence, or even good cause, was established because the Federal Rules of Civil Procedure purportedly favors doing so. But Lupin once again ignores the Federal Circuit, which has rejected that very argument.

In *O2 Micro*, the Federal Circuit settled any question concerning the validity of Local Patent Rule 3.7. The Court of Appeals held that local patent rules can legitimately require parties to provide their invalidity and infringement contentions early in the case and proceed with diligence in amending those contentions, without running afoul of the Federal Rules:

[W]e see nothing in the Federal Rules that is inconsistent with local rules requiring the early disclosure of infringement and invalidity contentions and requiring amendments to contentions to be filed with diligence. If the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery and trial preparation.

O2 Micro, 476 F.3d at 1366. Thus, no “tension” or “conflict” exists between the Federal Rules and Local Patent Rule 3.7, including its requirement of good cause and diligence.

Lupin’s reliance on Federal Rules 1, 8, 26, and 37 is unavailing. Those Rules have nothing to do with the contention disclosures required under this Court’s Local Patent Rules. For example, Rule 8 applies to pleadings, which are explicitly governed by a *different* standard for amendments. As this Court has held, the standard for amending contentions under the Local Patent Rules is “*decidedly conservative*” in contrast to the more liberal standard applied to amending pleadings. *King Pharms.*, 2010 WL 2015258, at *4. And Local Rule 3.7 expressly requires a defendant to show good cause, including demonstrated diligence, to amend its contentions. L. Pat. R. 3.7; *O2 Micro*, 467 F.3d at 1366. While Lupin attempts to cast the good cause requirement of Local Patent Rule 3.7 as a “mere technicality” or procedural inconvenience, the Rule itself and the Federal Circuit’s jurisprudence refute that view. Likewise, none of the cases Lupin cites support its view—in fact, some do not even address the amendment of local patent rule contentions. *See, e.g., Biogenex Labs., Inc. v. Ventana Med. Sys., Inc.*, No. C 05-860-JF-PVT, 2006 WL 2228940, at *1 (N.D. Cal. Aug. 3, 2006) (denying a motion for summary judgment).

IV. CONCLUSION

Lupin failed to diligently seek leave to amend its Invalidity Contentions to rely on the German Application. Accordingly, under applicable precedent, Lupin cannot satisfy the good cause required by Local Patent Rule 3.7 for amending contentions. On this basis, Magistrate Judge Schwartz correctly denied Lupin’s motion to amend its Invalidity Contentions. Judge Schwartz’s well-reasoned decision is supported by the relevant authorities, including the controlling precedent of the Federal Circuit. Thus, TWH respectfully asks this Court to uphold Judge Schwartz’s ruling and deny Lupin’s appeal.

Dated: February 7, 2011

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on February 7, 2011, a true and correct copy of the foregoing **PLAINTIFF'S BRIEF IN OPPOSITION TO LUPIN'S APPEAL FROM THE MAGISTRATE JUDGE'S ORDER DENYING LUPIN'S MOTION FOR LEAVE TO AMEND ITS PATENT INVALIDITY CONTENTIONS** was served on the following persons by ECF and electronic mail:

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